NRDS Policy and Governance Working Group

Monday May 18, 2015

Meeting Minutes

Action Item	Who	By When
Send out meeting minutes	Neesha Desai	5/21/15
Provide feedback on how to formulate policies around required data elements. Also think about how to determine if people are collecting the data elements and that they are collecting them correctly.	Working Group	5/29/15
Propose combining the Content and Policy WGs for a few meetings to the NRDS Committee	Neesha Desai	5/27/15

Agenda Topics

Introduction of members on the call – Neesha Desai welcomed the callers to the meeting and provided a recap of the last meeting.

Integration Matrix: The group decided to wait until Ravi is available to discuss this matrix prior to moving forward with this discussion. He will give the demo of the various integrations at another meeting.

Data Sharing Use Cases – Judi Manola reviewed the current use case examples for standardized data and other initiatives and existing generic data sharing issues.

RECIST Data Share – This sort of application of standardized data should be easy, even if you do not have coded values

- Shauna: Were you able to achieve what you needed without further standardization?
  - Judi: The data came from 2 different databases; it was not trivial but the standardizing was not very hard.
- Shauna: Did you think the caDSR and/or further standardization would have been more helpful to achieve the goal of this project?
  - Judi: I think this was enough. We used the site of the legion as the variable code (on the forms). The code for the site might not be the same over all of the groups but if requested out of Rave, we could likely map it without too much effort.
- Shauna: We do not know the next projects that will come along, so it is hard to define the level of standardization that will be needed.
  - Judi: This was the simplest thing I found to be harmonized across the groups; we could likely do this without any additional standardization.

Additional examples

- Judi: Cardiotoxicity, EA Cardiotoxicity Working Group, and Building “Gold Standard” cardiac case report forms for future trials; I am not sure how these groups may fold into our plan.
- Andrea: The breast cancer community has done something with the BOLD Task Force to ensure they standardize elements for looking across the system.

- Katie: We tried to use that for Alliance but they could not come to an agreement, so we were not able to come up with standardize case report forms (CRFs). They were going beyond what we would normally collect; it seems they were trying to do too much and that did not work for most trials.
- Shauna: It is hard to come up with a set of CRFs without a primary end-point in mind; we need to keep our scope very manageable.

Additional Consideration

- Data Aggregation - Diana: We have a 30-year history of our database and we get requests for different agents, medical history AEs, etc. We do this all the time, our CRFs have changed over time but we have tried to keep the same CRF structure (even though element coding may change). We do our best to try and do retrospective data mining projects.
- NCI Navigator - Judi: We may need to think about the standard data elements they are looking to use and determine if they would work with Rave. There is a data-working group, looking to capture basic data, age, demographic data but I am not sure about outcomes.
  - Dianne: They have not met for a while; they have about 9 data elements that we agreed upon but nothing with outcomes. I do not believe we need to be concerned with the NCI Navigator right now.
- Interim Policy Subject Areas – What subject areas do we need policies around?
  - Katie: DCP went through a similar exercise; they had a set of elements that were required but they could be placed anywhere on the form. Brenda M. was charged to ensure the checklist of elements were provided. Our current issue is that these are not mandatory elements; there are modules with optional elements, so this is harder to manage.
  - Shauna: We have been lobbying for a smaller set of elements that are mandatory, for ALL studies. It would be easier to require certain elements and do a checklist to ensure these elements are provided correctly.
  - Judi: We have an idea of the "mandatory" content should be. Our current requirement only requires that if the data is collected, that it will be collected in a certain way.
  - **Questions for the group:** If we had a policy that required certain elements, what would those elements be? How would you formulate a policy about the nature of it? How would we determine if people are collecting the items (and correctly)?
    - Neesha: The content working group is focusing on a small group of elements and we should focus on how we will govern this process.
- Would it make sense to merge the content and policy/governance working group? A lot of the discussions are overlapping and it may be helpful to merge these groups for some meetings.
  - Neesha Desai will propose this to the NRDS Committee on May 27th and get their feedback.

Next Steps

- Working Group members to provide feedback on how to formulate policies around required data elements. Also think about how to determine if people are collecting the data elements and that they are collecting them correctly.
- Neesha Desai to propose combining the Content and Policy WGs for a few meetings to the NRDS Committee.

Attendance:

Name	Affiliation
Katie Allen Ziegler	Alliance
Shauna Hillman	Alliance
Steven Jong	COG
Judi Manola	Eastern Cooperative Oncology Group-American College of Radiology's Imaging Network (ECOG-ACRIN)
Dianne Reeves	NCI
Andrea Denicoff	NCI
Janice Chilli	NCI
Mike Montello	NCI
Christina Warmington	NCI - Essex Management
Neesha Desai	NCI - Essex Management
Jennifer Thomas	NRG
Rodney Sutter	SWOG
Diana Vulih	Theradex
Pam Rapoport	Theradex